IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ALABAMA
NORTHEASTERN DIVISION

EDWIN R. BANKS,	)	
	)	
Plaintiff,	)	
	)	
v.	)	
	)	**Civil Action No.**
XAVIER BECERRA, in his official capacity as Secretary of the U.S. Department of Health and Human Services,	)	**5:20-CV-0565-LCB**
	)	
	)	
	)	
	)	
Defendant.	)	

DEFENDANT'S MOTION TO DISMISS
AND BRIEF IN SUPPORT THEREOF

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I. INTRODUCTION

This case involves judicial review of the denial of Medicare claims for certain months of tumor treatment field therapy ("TTFT"). Plaintiff Banks received the TTFT treatment and was not required to pay for it from his own funds. Banks has therefore suffered no concrete, non-speculative harm as a result of the denial of his TTFT device claims for January, March, and April 2018 because he was not ultimately required to pay for those treatments from his own funds. He thus lacks Article III standing because he has suffered no injury-in-fact that is likely to be redressed by a favorable judicial decision. For lack of standing, this matter should be dismissed.

II. STATUTORY AND REGULATORY BACKGROUND

The Secretary refers the Court to its Cross-Motion for Summary Judgment for a fuller discussion of the statutory and regulatory background in this case. *See* Doc. 37 at 3–8. The Secretary emphasizes and amplifies the background relevant to this motion.

A. Medicare Local Coverage Determinations

The Medicare statute excludes coverage of items or services that "are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member." 42 U.S.C. § 1395y(a)(1)(A). One way in which the "reasonable and necessary" standard is

administered is through Local Coverage Determinations, which are promulgated by Medicare Administrative Contractors for CMS. *See* 42 U.S.C. § 1395kk-1; *see also* 42 U.S.C. §§ 1395y(a), 1395ff(a), (f). A Local Coverage Determination specifies when an item or service is "reasonable and necessary" based a variety of factors, including medical literature, expert advice, and public comments, among other considerations. *See* the Medicare Claims Processing Manual (hereinafter "Manual") §§ 13.2.3, 13.5.2.1, 13, 13.5.5;[1] 66 Fed. Reg. 58,788, 58,788 (Nov. 23, 2001).

B. The Local Coverage Determination for the TTFT device

In April 2011, the United States Food and Drug Administration (FDA) approved the marketing of a tumor treatment field therapy (the TTFT device) called NovoTTF-100A, later rebranded Optune, for the treatment of recurrent glioblastoma multiforme (GBM), a kind of brain cancer. Administrative Record (AR)[2] (Doc. 38) at 1288, 1291. The TTFT device uses electric fields to prevent tumor growth. *Id.* at 1288.

[1] The Medicare Claims Processing Manual is available at https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Internet-Only-Manuals-IOMs-Items/CMS018912 (last visited October 12, 2021).The Manual "is a compilation of guidelines which CMS issues to instruct Medicare contractors on how to conduct medical review of Medicare claims submitted by Medicare providers and suppliers for payment." *Erringer v. Thompson*, 371 F.3d 625, 628 (9th Cir. 2004).

[2] Citations to " Doc. 38, AR" followed by a number refer to pages of Certified Administrative Record, attached as Exhibit C to Appellee's June 15, 2020, Notice of Filing Under Seal. Doc. 38.

In August 2014, the durable medical equipment Medicare Administrative Contractor issued the original Local Coverage Determination for the TTFT device, finding that the device was not reasonable and necessary for the treatment of recurrent GBM, and thus not covered by Medicare. *Id.* at 1291. The Local Coverage Determination stated that "[t]umor treatment field therapy (E0766) will be denied as not reasonable and necessary for the treatment of recurrent GBM." *Id.* at 1287. This Local Coverage Determination remained in effect during the dates of service for the Medicare claims at issue in the instant matter. *See id*. at 1261. The Local Coverage Determination has since been retired and is no longer in effect. A new Local Coverage Determination became effective on September 1, 2019, that permits coverage for newly diagnosed GBM and continued coverage for newly diagnosed GBM beyond the first three months of therapy in certain circumstances. *See id.* at 1282–1303.

C. Beneficiary Liability for Denied Medicare Claims

A Medicare beneficiary whose claim is denied is not automatically faced with the prospect of a large medical bill. Rather, if Medicare coverage is denied, Medicare will nevertheless pay the claim if neither the supplier nor the beneficiary knew or could reasonably have been expected to know that the item would not be covered. 42 U.S.C. § 1395pp; 42 C.F.R. § 411.400(a). If these conditions are not met, however, and Medicare payment is denied, the beneficiary is further protected from

an unexpected medical bill from the supplier by rules that shift the risk of non-coverage to the supplier and prevent the supplier from billing the beneficiary. *See Almy v. Sebelius*, 749 F.Supp.2d 315, 334 (D. Md. 2010) (discussing 42 C.F.R. § 411.404 ("Criteria for determining that a beneficiary knew that services were excluded from coverage as custodial care or as not reasonable and necessary") and Manual Ch. 30v ("Financial Liability Protections")).

A supplier of the medical treatment or device can shift the risk of non-coverage and bill the beneficiary only when the beneficiary has received sufficient advance notice of the risk of noncoverage to permit "an informed consumer decision about receiving items or services for which they may have to pay out-of-pocket." *Int'l Rehab. Sci. Inc. v. Sebelius*, 688 F.3d 994, 998 (9th Cir. 2012). A supplier typically satisfies this requirement by providing the beneficiary with an advance written notice (called an "Advance Beneficiary Notice") setting out the specific reason why the item probably will not be covered. 42 C.F.R. § 411.404(b); *see Int'l Rehab. Sci. Inc*., 688 F.3d at 997–98 (explaining that a valid Advance Beneficiary Notice allows the supplier to charge the beneficiary for non-covered items); *Almy v. Sebelius*, 679 F.3d 297, 311 n.4 (4th Cir. 2012) (same).

Additional requirements are imposed on suppliers of medical equipment and devices, which must not only provide such advance notice but obtain a written agreement in advance from the beneficiary agreeing to pay in the event Medicare

coverage is denied. 42 U.S.C. § 1395m(j)(4), incorporating 42 U.S.C. § 1395m(a)(18)(A)(ii); *see also* Manual Ch. 30, § 30.1 (requiring written agreement by beneficiary to pay personally in event of coverage denial).

Although § 1395m(j)(4) refers to claims that are "not on an assigned basis," beneficiary liability is also limited for assigned claims. As a non-participating supplier, Novocure may elect to accept assignment on a case-by-case basis. *See* 42 C.F.R. § 400.202 (defining a "nonparticipating supplier" as "a supplier that does not have an agreement with CMS to participate in Part B of Medicare in effect on the date of the service"). An assignment agreement transfers to the supplier the beneficiary's right to bill and receive Medicare payment, but the supplier agrees "not to charge (and to re-fund amounts already collected) for such service if payment may not be made therefor by reason of" § 1395y(a). 42 U.S.C. § 1395u(b)(3)(B)(ii).

In sum, the Medicare laws limit beneficiary liability for both unassigned and assigned claims. *See* Manual, Ch. 30 § 150 ("For both assigned and unassigned claims, for which the supplier knew or should have known of the likelihood that payment would be denied (that is, the supplier is held to be liable) and for which the beneficiary did not know, the beneficiary has no financial responsibility and the refund provisions of the Act apply in virtually all cases."). There is no evidence that Banks has signed an Advance Beneficiary Notice or an advance agreement to pay.

See AR (Doc. 38) at 1262, 1889. Therefore, Novocure may not bill Banks for his use of the TTFT device. *Id.* at 1262 (citing 42 U.S.C. § 1395pp).

III. STATEMENT OF FACTS

Banks began using the TTFT device in December 2013, around four years after he was diagnosed with GBM. Compl. (Doc. 1) ¶ 32. He submitted three claims, dated January 25, 2018, March 12, 2018, and April 12, 2018, for Medicare coverage to CGS Administrators, the durable medical equipment contractor who processed the claims. AR (Doc. 38) at 1791. CGS Administrators denied coverage based on the Local Coverage Determination in effect for that time frame and affirmed the denial on redetermination. *Id*. at 1862–63. CGS Administrators found that Novocure, as the supplier of the TTFT device, must bear the cost for the denied claims. *Id*. at 1863. At the next level of review, a qualified independent contractor upheld the denial of the claims and found that Novocure was required to bear the cost of nonpayment. *Id*. at 1792–93.

Banks then proceeded to the next level of review and sought a hearing before an ALJ. *Id.* at 1383–84. ALJ Bruce Kelton issued a decision, on June 3, 2019, finding that Medicare Part B did not cover the TTFT device for Banks's GBM. *Id*. at 1251–62. The ALJ also found that the cost for the treatment would be borne solely by Novocure because no Advance Beneficiary Notice had been provided to Banks. *Id*. at 1261–62.

Banks and Novocure appealed ALJ Kelton's decision to the Medicare Appeals Council. *Id*. at 1304–10. After the Council did not issue a decision within the 90-day regulatory time frame, Banks sought further review with the district court. *Id*. at 1263–64, 1267.

Plaintiff initially filed his case in the United States District Court for the District of Columbia, but his claims were severed and transferred to the Northern District of Alabama on May 11, 2020. Doc. 21. In his Complaint, Banks alleged, in relevant part, that collateral estoppel barred an unfavorable decision rendered by ALJ Kelton. *See generally* Compl. (Doc. 1) *and id.* at 14 (*ad damnum* clause). Specifically, Banks contended that a later June 6, 2019, favorable decision by ALJ Gulin precluded ALJ Kelton's June 3, 2019, unfavorable decision. *Id.* ¶¶ 36–37.

The parties filed cross-motions for summary judgment addressing whether collateral estoppel was applicable to non-precedential ALJ decisions determining Medicare coverage for particular claims. Docs. 31 (Plaintiff's Motion) and 37 (Defendant's Motion). This Court granted the Secretary's motion and denied Banks's motion, concluding that ALJ Kelton's decision was not barred by collateral estoppel, which—based on the statutory and regulatory scheme of the Medicare Act—was inapplicable to Banks's appeal. Order (Doc. 52) at 11. After this Court entered its final judgment (Doc. 53), Banks appealed (Doc. 54). The Secretary

argued before the Eleventh Circuit, for the first time,[3] that Banks lacked Article III standing because he had suffered no injury in fact that is redressable by this court. The Eleventh Circuit remanded the case to this Court "for additional factfinding and a ruling on the issue of Article III standing in the first instance." *Banks v. Sec'y of Health and Human Servs.,* No. 20-11454, 2021 WL 3138562, at *4 (11th Cir. July 26, 2021).

IV. STANDARD OF REVIEW

Standing is a jurisdictional threshold to suit in federal court. *See Bochese v. Town of Ponce Inlet*, 405 F.3d 964, 974 (11th Cir. 2005). "[O]nce a federal court determines that it is without subject matter jurisdiction, the court is powerless to continue." *Univ. of S. Alabama v. Am. Tobacco Co.*, 168 F.3d 405, 410 (11th Cir. 1999). The lack of subject-matter jurisdiction defense is never waived. Fed. R. Civ. P. 12(h)(1). "If the court determines at any time that it lacks subject-matter jurisdiction, the court must dismiss the action." Fed. R. Civ. P. 12(h)(3) (emphasis added).

The burden of establishing federal jurisdiction rests on the party seeking the federal forum. *See Miccosukee Tribe of Indians of Fla. v. Fla. State Athletic*

[3] "Questions of subject matter jurisdiction may be raised at any time. *Ingram v. CSX Transp., Inc.*, 146 F.3d 858, 861 (11th Cir. 1998). Although we ordinarily will not address issues raised for the first time on appeal, '[a]ny time doubt arises as to the existence of federal jurisdiction, we are obliged to address the issue before proceeding further.' *Atlanta Gas Light Co. v. Aetna Cas. & Sur. Co.*, 68 F.3d 409, 414 (11th Cir. 1995)." *Nicklaw v. Citimortgage, Inc.*, 839 F.3d 998, 1001 (11th Cir. 2016); *see also* Fed. R. Civ. P. 12(h)(3).

Comm'n, 226 F.3d 1226, 1229–30 (11th Cir. 2000). "The plaintiff has the burden to 'clearly and specifically set forth facts sufficient to satisfy Art. III standing requirements.' If the plaintiff fails to meet its burden, this court lacks the power to create jurisdiction by embellishing a deficient allegation of injury." *Id.* (quoting *Whitmore v. Arkansas*, 495 U.S. 149, 155 (1990)).

V. ARGUMENT

A. Overview of the Legal Standards of Standing.

Banks suffered no concrete, non-speculative injury sufficient to confer Article III standing from the denial of the January, March, and April 2018 claims. The Constitution limits the jurisdiction of federal courts to hearing only cases and controversies. U.S. Const. art. III, § 2, cl. 1; *see Raines v. Byrd*, 521 U.S. 811, 818 (1997). Standing is an element of the case-and-controversy requirement. *Raines*, 521 U.S. at 818; *Clapper v. Amnesty Int'l USA*, 568 U.S. 398, 408 (2013). "The federal courts are under an independent obligation to examine their own jurisdiction, and standing 'is perhaps the most important of the jurisdictional doctrines.'" *Region 8 Forest Serv. Timber Purchases Council*, 993 F.2d at 800, 807 n.9 (11th Cir. 1993) (quoting *FW/PBS, Inc. v. City of Dallas*, 493 U.S. 215, 230 (1990)). To establish standing, Banks must show that he has "(1) suffered an injury in fact, (2) that is fairly traceable to the challenged conduct of the defendant, and (3) that is likely to be redressed by a favorable judicial decision." *Spokeo, Inc. v.*

Robins, 578 U.S. 330, 136 S. Ct. 1540, 1547 (2016).[4] Here, Banks lacks standing because he cannot meet the first and third elements of this test.

B. Banks Has Presented No Evidence That He Suffered Any Injury in Fact as a Result of the Denial of the Medicare Claims.

Banks suffered no injury because he is not financially liable for the denied claims. To establish standing, Banks must show he suffered an injury in fact that is "'concrete and particularized' and 'actual or imminent, not conjectural or hypothetical.'" *Trichell v. Midland Credit Mgmt., Inc.,* 964 F.3d 990, 996 (11th Cir. 2020) (quoting *Lujan v. Defenders of Wildlife, et al.*, 504 U.S. 555, 560 (1992)). "Particularized" means that the injury affects the plaintiff in a "personal and individual way." *Lujan*, 504 U.S. at 560 n.1; *see Warth v. Seldin,* 422 U.S. 490, 498 (1975) (explaining that the plaintiff must have "such a personal stake in the outcome of the controversy as to warrant his invocation of federal-court jurisdiction"). "Concrete" means that the injury "must actually exist." *Spokeo*, 136 S. Ct. at 1548. Regardless of whether the harm is "tangible" or "intangible," it must be "real, and not abstract." *Id.* at 1548–49 (internal quotations omitted).

Banks cannot meet his burden because the denial of the January, March, and April 2018 claims has not resulted in any injury to him.[5] The ALJ specifically

[4] At the time of this filing, pin citations were not available to the United States Reports.

[5] The Seventh Circuit and several district courts have dismissed similar TTFT device coverage suits for lack of standing. *See Prosser v. Becerra*, 2 F.4th 708 (7th Cir. 2021); *Goldman v. Azar*, No.

found that the cost for the treatment would be borne solely by Novocure because no Advance Beneficiary Notice had been provided to Banks. AR (Doc. 38) at 1261–62. Thus, Novocure, not Banks, is financially liable for the three claims at issue, and Banks has no potential liability. Whether the ALJ decision is affirmed or reversed, the result will be the same for Banks: he will not pay for the three denied claims on review. *See Thole v. U.S. Bank N.A.*, 140 S. Ct. 1615, 1619 (2020) (holding that plaintiffs lacked standing because the outcome of the lawsuit would not affect the payments they received from their defined-benefit retirement plan).

Further, the Eleventh Circuit rejected Banks's argument that the alleged violation of Banks's statutory right to Medicare coverage is sufficient to establish standing. *Banks*, 2021 WL 3138562, at *3 ("[W]e know one thing to be true—alleging a mere statutory violation is not enough to show injury in fact.") (*citing Murkansky v. Godiva Chocolatier, Inc.*, 979 F. 3d 917, 924 (11th Cir. 2020)(en banc)). The Court found that because Banks does not have to pay for the denied claims, "Banks has not shown how the statutory violation caused a direct harm." *Id.* at *3.

20-cv-00463, 2021 WL 3725588 (S.D. Tx. Aug. 23, 2021); *Thumann v. Cochran*, No. 20-cv-125, 2021 WL 1222142 (S.D. Ohio March 31, 2021); *Wilmoth v. Azar*, No. 3:20-cv-00120, 2021 WL 681118 (N.D. Miss. Feb. 22, 2021); *Oxenberg v. Cochran*, No. 2:20-cv-00738, 2021 WL 462731 (E.D. Pa. Feb. 8, 2021), *appeal docketed*, No. 21-1682 (3d Cir. April 13, 2021). *Komatsu v. Azar*, No. 20-cv-00280, 2020 WL 5814116 (C.D. Cal. Sept. 24, 2020); *Pehoviack v. Azar*, No. 20-cv-00661, 2020 WL 4810961 (C.D. Cal. July 22, 2020).

Banks may not rely on speculative or hypothetical future harms to establish standing. If an injury is not "actual," it must be "imminent," which means "that the injury is certainly impending." *Lujan*, 504 U.S. at 564 n.2 (internal quotations omitted). Allegations of "an injury at some indefinite future time" are insufficient. *Id.*; *see also Clapper*, 568 U.S. at 409 (explaining that claims about a potential future injury are insufficient). There must be a "high degree of immediacy, so as to reduce the possibility of deciding a case in which no injury would have occurred at all." *Lujan*, 504 U.S. at 564 n.2. Banks cannot rely on a "speculative fear" about a possible future harm by pointing to a "highly attenuated chain of possibilities." *Clapper*, 568 U.S. at 410. Rather, there must be a "substantial risk" of such harm occurring. *Tsao v. Captiva MVP Rest. Partners, LLC*, 986 F.3d 1332, 1339 (11th Cir. 2021). Moreover, the risk of harm must not have dissipated before the complaint was filed. *Trichell*, 964 F.3d at 1003.

Banks's assertion that future claims may be denied because the claims on which he premises this action were denied is merely speculative. The denial of the January, March, and April 2018 claims does not make it any more or less likely that future claims will be granted or denied. Moreover, it is impossible that any future claims would be denied on the exact grounds as the claims at issue here because the controlling Local Coverage Determination was revised effective September 1, 2019. *See* AR (Doc. 38) at 1282–1303.

Any assertion by Banks that he risks future liability under 42 U.S.C. § 1395pp is likewise without merit. Section 1395pp applies to situations where Medicare pays one time for a non-covered item when *both* the supplier and beneficiary could not have known Medicare would deny a claim.[6] That is not what occurred with respect to the three claims at issue in this case. Here, the ALJ found that Novocure should have known that the claims would not be covered; it did not find that Medicare would cover the costs once only because neither party could have known the claims would be denied. *Id.* at 1261–62.

In addition, as previously noted, Medicare requires that medical equipment suppliers provide the beneficiary with advance notice of non-coverage, generally an Advance Beneficiary Notice (ABN), and an agreement by the beneficiary to pay if coverage were denied, before a beneficiary will be liable for a denied claim. 42 U.S.C. §§ 1395m(a)(18)(A)(ii), 1395m(j)(4); 42 U.S.C. § 1395u(b)(3)(B)(ii); *see also Prosser v. Becerra*, 2 F.4th 708, 711 (7th Cir. 2021) ("Medical device suppliers—as opposed to healthcare providers in general—bear an additional

[6] In any event, § 1395pp(b) states that "in the case of *comparable situations* arising thereafter with respect to such individual, [the Secretary] shall, by reason of such notice . . . be deemed to have knowledge that payment cannot be made for such items and services" (emphasis added). The knowledge requirement is applied "on a case by case basis." Manual, Ch. 30 at § 30.1. Here, there was a radical change between the 2015 Local Coverage Determination (LCD), which categorically denied coverage for TTFT, and the current LCD, which provides for coverage if certain requirements are met. "It is speculative, and indeed quite unlikely, that an ALJ would deem [plaintiff] to have knowledge that his future TTFT claims will be denied given the change in the 2019 LCD and the current lack of a 'comparable situation' within the meaning of Section 1395pp." *Wilmoth*, 2021 WL 681118, at *4.

burden should they wish to shift the risk that coverage may be denied; they must obtain a written agreement by the patients that she will individually bear the cost of the coverage denial."); Manual, Ch. 30 at § 30.1. (for DME suppliers, beneficiary knowledge must be evidenced by a signed written notice and agreement to pay personally in case of a denial.)

The record contains no evidence (or even an allegation) that Novocure ever provided such notice to Banks or obtained an agreement from Banks to pay in the absence of coverage. In short, Banks's claim that he faces potential liability in the future based on the denial of the three claims at issue here is speculative and insufficient to confer standing in this action. In *Thumann v. Cochran*, the court aptly summarized a future injury hypothesis identical to that advanced by Banks:

> [F]or Plaintiff to face future harm, several things would need to happen. First, Plaintiff would need to sign an ABN assuming liability for future claims denials (which Novocure has not asked Plaintiff to do). Second, Plaintiff would need to be denied coverage for TTFT (even though the Current [Local Coverage Determination] permits coverage). Third, the claims denials would have to upheld at all stages of the Medicare appeals process (i.e., redetermination, reconsideration, ALJ review, Council Appeal, and court review). And after all that, it would still need to be determined that Plaintiff had actual/constructive knowledge that his claim would be denied (which even the Secretary deems unlikely).

Thumann, No. 20-cv-125, 2021 WL 1222142, at * 7 (S.D. Ohio March 31, 2021). The court therefore concluded that "[s]uch an attenuated chain of events does not constitute a threatened harm." *Id.*

Several other courts considering TTFT claims have found Banks's future injury claim to be too speculative to support standing. *See, e.g.*, *Prosser*, 2 F.4th at 715 ("Prosser . . . posit[s] that she may incur financial liability in future coverage determination for TTF therapy. But that suggestion is far too attenuated from the instant appeal and far too speculative at this juncture to suffice for an imminent injury."); *Wilmoth v. Azar*, No. 3:20-cv-00120, 2021 WL 681118, at *4 (N.D. Miss. Feb. 22, 2021) ("Any relationship between the subject claim denial and [plaintiff's] financial liability for any future medical charges is speculative. Equating speculative future harm with concrete injury is inconsistent with Article III standing jurisprudence."); *Pehoviack v. Azar*, No. 20-cv-00661, 2020 WL 4810961 at *3 (C.D. Cal. July 22, 2020) ("Plaintiff argues . . . that she may be held personally liable for future treatments, or that her TTFT supplier might require her to sign an agreement assuming liability for the costs of future Medicare denials. None of these potential injuries, however, has come to pass; indeed, Plaintiff has received favorable Medicare decisions for treatment periods subsequent to the denial at issue here.") (citation omitted); *Komatsu v. Azar*, No. 20-cv-00280, 2020 WL 5814116, at *2 (C.D. Cal. Sept. 24, 2020) ("[W]hile [plaintiff] could be liable for future treatments, she has not demonstrated that the threatened injury, the possibility of her being financially responsible for TTFT, is 'certainly impending.'").

If, in the future, Novocure charges Banks after a Medicare claim denial because Banks signed an Advance Beneficiary Notice and an agreement to pay, Banks could pursue a suit on those claims at that time. But at this time, any such claim is premature and, at best, speculative, not "actual" or "imminent" as required for standing. *See Lujan*, 504 U.S. at 564 n.2.

C. Banks Has Not Suffered an Injury that is Redressable By a Favorable Judicial Decision.

Even if Banks, *arguendo*, could show harm, a favorable decision would not redress the harm. To establish standing, "Plaintiff must not only establish an injury that is fairly traceable to the challenged conduct but must also seek a remedy that redresses that injury." *Uzuegbunam v. Preczewski,* --- U.S. ---, 141 S. Ct. 792, 796 (2021). For redressability, Banks must show a "substantial likelihood that the requested relief will remedy the alleged injury in fact." *Vt. Agency of Nat. Res. v. U.S. ex rel. Stevens*, 529 U.S. 765, 771 (2000) (internal quotations omitted). Banks cannot meet this burden because there is no evidence that a favorable decision will redress any alleged harm he has suffered.

It is undisputed that Banks has already received the TTFT device for the coverage dates in question, and he has no actual or potential liability for the costs of those three claims. A reversal here will not change that. *See Steel Co. v. Citizens for a Better Env't*, 523 U.S. 83, 106–07 (1998) (finding the redressability requirement not met where the penalties paid if a suit were successful would be

paid to the Treasury, not the plaintiff). The Supreme Court recently addressed the redressability requirement in *Uzuegbunam,* 141 S. Ct. 792, where it held that students had standing to seek nominal damages as part of their challenge to a University's policy concerning religious speech after the University revoked the policy in question. *Id.* at 801–02. The Court discussed only the third element of standing—redressability—where the plaintiffs sought to vindicate their First Amendment rights through an award of nominal damages. *Id.* at 797. Unlike the plaintiffs in *Uzuegbunam*, Banks has not sought nominal damages. Moreover, as noted above, a reversal of the decision here will also not render it any more or less likely that any future treatment will be covered. A favorable judicial decision in this case, therefore, will not redress the purported injury.

VI. CONCLUSION

For the foregoing reasons, the Secretary respectfully requests that this Court grant his motion to dismiss for lack of subject-matter jurisdiction and dismiss this case in its entirety, with prejudice.

Date: October 12, 2021

Respectfully submitted,

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